

REMARKS

This Preliminary Amendment constitutes the proper Submission with the RCE being concurrently filed and fully complies with M.P.E.P. § 706.07(h)(II).

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

In the present Preliminary Amendment, claims 2, 4, 5, 24 and 26 have been amended and claim 28 has been added. Also, claims 1, 3, 6, 7, 11 and 16-23 were previously canceled without prejudice or disclaimer of the subject matter contained therein. Thus, claims 2, 4, 5, 8-10, 12-15 and 24-28 are pending in the present application.

No new matter has been added by way of these amendments because each amendment is supported by the present specification. For example, the amendment to claim 2 has support in the present specification at least in paragraph [0044] at pages 11-12. The amendments to claims 4, 5, 24 and 26 are clarifying in nature. By deleting/amending these terms in order to clarify the claimed invention (e.g., “without a sugar chain” to “said biocompatible component having no sugar chain”), Applicants are in no way conceding any limitations with respect to the interpretation of the claims under the Doctrine of Equivalents.

New claim 28 is drawn to another embodiment of the present invention and has been added for the Examiner’s consideration. Support for new claim 28 is found at least in paragraph [0076], page 18 of the present specification. No new matter has been added.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 112, First Paragraph

Claim 2 stands rejected under 35 U.S.C. § 112, first paragraph, for asserted lack of enablement (see Office Action, paragraphs 2-3, page 2). Applicants respectfully traverse.

The Examiner rejects the language “graft polymerization” asserting that the specification refers to an activated surface or intermediate layer for the graft polymerization to take place. Thus, the Examiner is asserting claim 2 needs to recite such a feature(s).

Applicants respectfully refer the Examiner to claim 2 as shown herein, wherein the disputed claim language is no longer recited. The present invention is directed to a “medical material comprising a biocompatible component grafted to a surface of a diamond-like carbon film ...”. Applicants note that a product is being claimed, and that reciting a surface to be activated is a process step. Reconsideration and withdrawal of this rejection are respectfully requested.

Issues under 35 U.S.C. § 112, Second Paragraph

Claims 24-27 stand rejected under 35 U.S.C. § 112, second paragraph, for asserted lack of definiteness (see Office Action, paragraphs 4-5, page 3). Applicants respectfully traverse and refer the Examiner to the disputed claims as shown herein as this rejection has been overcome.

For instance, regarding claim 24, it has been clarified that the biocompatible component has no sugar chain. Applicants note that such language was already clear in, e.g., claim 25, which depends on claim 24. The same reasoning applies to claims 27 which depends on claim 26. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Issues under 35 U.S.C. § 102(b)

Claims 2, 3, 24 and 25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by **Tanga ‘908** (U.S. Patent No. 6,607,908 B1) as evidenced by the ***Handbook of Physical Vapor Deposition (PVD) Processing*** (page 539) (see paragraphs 6-12, pages 3-5 of the Office Action).

Also, claims 2, 3, 8 and 12-15 stand rejected under 35 U.S.C. § 102(b) as being anticipated by **Steffen *et al.*** (*Sur. Interface Anal.*, Vol. 29, pp. 386-391 (2000)) (see pages 5-8 of the Office Action).

Applicants respectfully traverse and reconsideration is requested as each of Tanga ‘908 and Steffen *et al.* fails to disclose all instantly claimed features.

The present invention is directed to a medical material comprising a biocompatible component grafted to a surface of a diamond-like carbon film, and said diamond-like film is formed on a surface of a base material, wherein said biocompatible component is a polymer of vinyl monomers, vinylidene monomers, vinylene monomers or cyclic vinylene monomers (see pending claim 2). Tanga ‘908 and Steffen *et al.* fail to disclose or suggest this grafted structure and/or the polymer. The cited references do not suggest such a structure is even available.

Anticipation requires that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *In re Robertson*, 169

F.3d 743, 745, 49 USPQ2d 1949 (Fed. Cir. 1990) (citing *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Thus, because of the lack of disclosure of all features as instantly claimed, the rejections in view of Tanga '908 and Steffen *et al.* are overcome.

Further, Applicants note paragraph 11 of the Office Action wherein the Examiner states that claims 2-4 are product-by-process claims due to the recitation of "graft polymerization". Reconsideration is requested in light of the claim amendments as seen herein, wherein the previous assertion by the USPTO was that "graft polymerization" did not result in a different structure. In the present invention, a biocompatible component is grafted to a surface of a diamond-like carbon film, and this structure is not disclosed in the cited references.

Reconsideration and withdrawal of both rejections are respectfully requested

Issues under 35 U.S.C. § 103(a)

Claims 3-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Steffen *et al.*** in view of **Palmaz '310** (U.S. Patent No. 6,537,310 B1) (see pages 8-9 of the Office Action).

Also, claims 9-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Steffen *et al.*** in view of **Lemelson '570** (U.S. Patent No. 6,083,570) (see pages 9-10 of the Office Action).

Applicants respectfully traverse and reconsideration is based on the following remarks. Overall, Applicants do not concede that a *prima facie* case of obviousness has been established.

Applicable U.S. Case Law

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 set forth some rationales that were set established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Here, the Examiner has not appropriately resolved the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue, and the rationale in combining the cited references is improper.

Distinctions over the Combination of Steffen *et al.* and Palmaz ‘310 and over the Combination of Steffen *et al.* and Lemelson ‘570

Applicants note that claim 3 has been canceled, rendering the rejection of this claim moot. Claims 4, 5, 9 and 10 ultimately depend on claim 2, and thus the comments with respect to Steffen *et al.* above apply to these rejections as well.

Specifically, as mentioned, the cited primary reference of Steffen *et al.* (for both rejections) fails to disclose all claimed features. The citation of Palmaz ‘310 and Lemelson ‘570

does not account for the deficiencies and problems of the primary reference (e.g., no disclosure of the claimed structure or polymer). Other U.S. patents are also cited at pages 8-9 of the Office Action, but these cited references are also insufficient to make up the noted deficiencies.

For instance, U.S. Patent No. 5,932,299 does show grafting another material to a polymer coated on the surface of the medical instrument. Also, the cited Palmaz '310 reference does teach that various materials are coated onto the surface of a medical instrument. However, none of the cited references discloses grafting a polymer onto a DLC film formed on the surface of the medical instrument. None of these references even teach suggest a possibility. Therefore, even if somehow Steffen *et al.* was combined with one or more of the cited references (which Applicants submit is improper), it is impossible to obtain the structure wherein a DLC film is formed on a surface of a medical instrument and a biocompatible component (which is a polymer of vinyl monomers, vinylidene monomers, vinylene monomers or cyclic vinylene monomers) that is grafted to the filmed surface of the medical instrument. Therefore, regarding the *Graham* factor of ascertaining the differences between the prior art and the claims that are at issue, the cited combinations of references fail to even disclose or suggest all claimed features (e.g., the claimed structure).

Further, as the M.P.E.P. directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See MPEP § 2143.03. In the present invention, a biocompatible component is grafted to a surface of a diamond-like carbon film. Further, a polymer made by specific monomers is being recited.

Applicants also respectfully note that the fact that a claimed product is within the broad field of the prior art and one might arrive at it by selecting specific items and conditions does not render the product obvious in the absence of some directions or reasons for making such selection. *Ex parte Kuhn*, 132 USPQ 359 (POBA 1961). The rationales set forth in paragraphs 8 and 12 of the Office Action are improper, especially in view of the present claims.

Also, regarding the *Graham* factor of evaluating any evidence of secondary considerations, this *Graham* factor resides in Applicants' favor as unexpected results for the present invention have been established. As explained in the specification (see, e.g., the summary in paragraph [0088] at page 21), the present invention is useful not only as a method for treating the surface of a material with a diamond-like carbon film formed thereon and a surface-treated material, but also as a medical material having excellent biocompatibility and as a medical instrument formed of the medical material. Furthermore, it is possible to give the material some functionality other than biocompatibility. Accordingly, Applicants respectfully submit that the *Graham* factors reside in Applicants' favor.

Based on the above comments, reconsideration and withdrawal of both rejections are respectfully requested.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Application No. 10/594,918

Docket No.: 4633-0189PUS1

Art Unit 1794

Preliminary Amendment with RCE

(Reply to Office Action of October 29, 2008)

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: JAN 09 2009

Respectfully submitted,

By 

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